



AMERICAN
KRATOM
ASSOCIATION

KRATOM FACT SHEET

Natural Kratom Products vs. Adulterated Kratom Products *Where the FDA Went Wrong*

Background on Kratom use in the United States

Kratom was first introduced to the United States following the Vietnam War when Southeast Asia immigration increased and returning soldiers, who had been introduced to kratom during their service there, continued its use for an energy and mood boost, similar to having a cup of coffee in the morning, and for its pain relief effects. Kratom was acquired either from friends and families in Southeast Asia who sent it to the United States, or from ethnic deli's that served those communities.

The natural kratom plant is typically consumed by chewing on the leaves, brewing the leaves or powdered leaves in hot water to create a tea, or in capsules with powdered kratom leaves. Its effects cannot be replicated or enhanced by smoking or injecting either the plant or an extract created by the powdered leaves. Kratom has been used safely in Southeast Asia for

centuries without any reported overdose death caused by consuming the plant. Users can develop a mild addiction, similar to caffeine addiction, and its withdrawal is similar to caffeine.

In the mid-1990's the popularity of kratom was discovered by many Head Shop and Smoke Shop operators, some of whom unethically enhanced sales of kratom to their customers by frequently and illegally mixing it with various drugs, i.e., heroin, morphine, and fentanyl while creating the misimpression that the customers were buying only the pure kratom plant rather than a heavily adulterated substance laced with highly addictive and potentially deadly illegal substances.

It is estimated there are currently nearly 5 million kratom users in the United States.

Regulatory action by the FDA and DEA

The adverse events reported from consuming these adulterated kratom products resulting in a warning issued by the Drug Enforcement Administration (DEA) in 2005, but the DEA failed to make the critically important distinction on safety issues with natural kratom versus adulterated kratom products. In 2009, a cluster of nine deaths were reported in Sweden over a twelve-month period from consuming a kratom product sold in the internet known as “Krypton.” This elevated the concern of both the DEA and FDA into the potential safety issues associated with the use of kratom and triggered an Import Alert being placed on kratom by the FDA in 2012 (subsequently affirmed in other Import Alerts in 2014 and 2016).

The FDA then and now continues to ignore research published in 2011 that documented that the nine deaths in Sweden were actually caused by the intentional adulteration of the kratom power in Krypton with a toxic dose of *O*-desmethyltramadol, an opioid analgesic and the main active metabolite of tramadol.¹ Adding to the confusion about kratom, the FDA has and continues to repeatedly reference these nine Swedish deaths in proposed regulatory actions to ban the natural plant kratom.

Based on the dissemination of public safety

alerts on kratom to state and local health and law enforcement officials by the FDA and DEA, six states acted to ban kratom sales from 2012 to 2016. None of these alerts referenced the important distinction between the natural kratom plant and dangerous adulterated kratom products being marketed by unscrupulous vendors to unsuspecting customers.

On August 31, 2016 the DEA, acting on the request of the FDA, published a Notice of Intent to place the two active alkaloids of kratom, mitragynine (MG) and 7-hydroxymitragynine (7-HMG) as banned Schedule I substances under the emergency scheduling provisions of the Controlled Substances Act (CSA), citing a total of 33 deaths allegedly associated with the use of kratom.² On October 14, 2016 the DEA withdrew the scheduling notice and invited public comments and directed the FDA to provide an “expedited 8-Factor Analysis (8-FA)” to justify the scheduling of Kratom by December 1, 2016.³

There were 23,232 comments submitted, with 99.1% opposing the ban (only 113 comments were in favor).⁴ Commenters included researchers, medical professionals, law enforcement officials, veterans, as well as kratom consumers.⁵ The FDA failed to submit

¹ Robert Kronstrand, Markus Roman, Gunilla Thelander, and Anders Eriksson, Unintentional Fatal Intoxications with Mitragynine and *O*-Desmethyltramadol from the Herbal Blend Krypton, *Journal of Analytical Toxicology*, Vol. 35, May 2011.

² Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine into Schedule I, 81 Fed. Reg. 59,929 (proposed Aug. 31, 2016) (to be codified at 21 C.F.R. 1308)

³ <https://www.federalregister.gov/documents/2016/10/13/2016-24659/withdrawal-of-notice-of-intent-to-temporarily-place-mitragynine-and-7-hydroxymitragynine-into>

⁴ https://www.huffingtonpost.com/entry/dea-kratom-ban-comments_us_589374f1e4b06f344e4074fa

⁵ *Ibid.*

the expedited 8-FA by the December 1, 2016 deadline requested by the FDA. However, the American Kratom Association (AKA) commissioned an independent 8-FA to be conducted by Jack Henningfield, Ph.D. and expert in addiction and safety of substances, and that report documented the failure of the FDA to meet the required standards under the CSA for the scheduling of kratom.⁶

In October 2017, the FDA renewed its request for scheduling of MG and 7-HMG with its 8-FA to the DEA. In addition, the FDA announced a Public Health Advisory on Kratom on November 14, 2017 claiming an increase in “kratom associated deaths” to 36 and claiming kratom has similar effects and dangers as using classic opioids.⁷ Again, the FDA failed to make the distinction between natural kratom products and dangerous adulterated kratom.

On February 6, 2018, the FDA issued a statement claiming additional adverse events and announced the development of a “novel” computer modeling tool that provided stronger evidence of kratom compounds’ opioid properties.⁸ The FDA claimed the number of deaths associated with the use of kratom had increased to 44 (again, including the nine Swedish deaths in 2009). Leading scientists strongly contested the FDA use of the computer modeling to draw the conclusions on the opioid effects of MG and 7-HMG, and condemned FDA’s claims of deaths associated with kratom

rather than polydrug use, underlying medical conditions, or the use of adulterated kratom products.⁹

In June 2018, the first animal study on the safety of kratom was published by Scott Hemby, et. al., that showed that MG is not dangerously addictive, and 7-HMG occurs at such a low level that it has no significant activity that would justify a scheduling decision.¹⁰ In July 2018, just a few weeks later, a second animal study conducted by the National Institute on Drug Abuse’s (NIDA) own intramural research program compared MG to heroin, methamphetamine, and placebo saline and found that it most closely resembled saline in this gold-standard animal model of abuse potential. This research concluded the results “suggest a limited abuse liability of mitragynine . . .”¹¹

These studies directly refute the FDA’s claim that kratom is dangerously addictive, and that it has the same opioid-like effects. In addition, NIDA updated its conclusions on whether kratom can cause an overdose on September 20, 2018 with the following statement:

*“In 2017, the Food and Drug Administration (FDA) began issuing a series of warnings about kratom and now identifies at least 44 deaths related to its use, with at least one case being investigated as possible use of pure kratom. **Most kratom***

⁶ Henningfield JE, Fant RV, Wang DW. The abuse potential of kratom according the 8 factors of the controlled substances act: implications for regulation and research. *Psychopharmacology (Berl)*. 2017;235(2):573-589.

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<https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm584970.htm>

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<https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm595622.htm>

⁹ FDA Fails to Follow the Science on Kratom, August 2018, Jane Babin, Ph.D., Esq., J.D., University of San Diego School of Law, Ph.D., Molecular Biology, Purdue University

¹⁰ Hemby et al. “Abuse liability and therapeutic potential of the *Mitragyna speciosa* (kratom) alkaloids mitragynine and 7-hydroxymitragynine,” *Addiction Biology*, 27 June 2018, doi: 10.1111/adb.12639.

¹¹ Yue K, Kopajtic, Katz, Abuse liability of mitragynine assessed with a self-administration procedure in rats, *Psychopharmacology*, 2018, <https://www.ncbi.nlm.nih.gov/pubmed/30039246>

associated deaths appear to have resulted from adulterated products (other drugs mixed in with the kratom) or taking kratom along with other potent substances, including illicit drugs, opioids, benzodiazepines, alcohol, gabapentin, and over-the-counter medications, such as cough syrup. Also, there have been some reports of kratom packaged as dietary supplements or dietary ingredients that were laced with other compounds that caused deaths.¹² **(emphasis added)**

Significantly, NIDA's research has shown clearly that the FDA claimed deaths resulted from the use of adulterated kratom products. The CSA did not grant any statutory authority for scheduling of a substance where the safety and addiction liability is derived from an adulterant of the substance, and there has never been any such scheduling in the history of the CSA. The FDA does have specific statutory authority to seize any adulterated product that poses a safety

hazard to consumers, and it can and should use this powers to remove adulterated kratom products from the marketplace and refer any individuals or corporations responsible for producing and marketing these adulterated products for prosecution by the Department of Justice.

There is a segment of the kratom consumer community who have found pure kratom to be an effective pain management option, as many other herbal and dietary supplement consumers have with other products, as an alternative to dangerously addictive or potentially deadly opioids. The FDA has conflated the legitimate uses by consumers to use safe pure kratom with the illegal marketing of various kratom products by vendors who make impermissible health claims about the therapeutic value of kratom. The FDA has existing statutory powers to stop these vendors from these illegal claims, just as they do for any other dietary ingredient or dietary supplement.

Conclusions

The DEA should return FDA's 8-FA for further analysis, and the FDA should (1) rescind the Import Alert; and (2) use its existing regulatory authority to interdict adulterated kratom products to protect the safety of American consumers.

Individual states should enact legislation that protects consumers from adulterated kratom products, and require labeling that allows consumers to know exactly what is in any kratom product. The AKA endorses the principles in the model Kratom Consumer Protection Act that has been introduced in Michigan, Utah, Arizona, and is been considered in many other states.

¹² National Institute on Drug Abuse, DrugFacts, revised September 2018, What is kratom?, <https://www.drugabuse.gov/publications/drugfacts/kratom>